

REMARKS / ARGUMENTS

1. Dayco / McKesson Disclosure

In accordance the undersigned's current understanding of the obligations imposed by *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003) and *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897 (Fed. Cir. 2007), the following co-pending application(s) whose file history may contain material information are identified. In assessing the patentability of the pending claims, the Office is respectfully requested to review the file history of each the listed co-pending application(s), determine whether such co-pending application has "similar subject matter" and, if so, consider each Office Action, including each reference on which a rejection is based, and each paper submitted by applicant therein.

- a. The subject matter of this application may be related to the subject matter of application serial no. 10/501,112, which is currently pending before Examiner Evanisco. This application is currently on Appeal.
- b. The subject matter of this application may be related to the subject matter of application serial no. 11/663,115, which has not yet been assigned to an Examiner, has not yet been examined.
- c. The subject matter of this application may be related to the subject matter of application serial no. 12/134,084, which is currently pending before Examiner Getzow, has not yet been examined.

2. Response to 08/19/2010 Non-Final Office Action

For the convenience of the Examiner and clarity of purpose, Assignee has reprinted the substance of the Office Action in *9-point bolded and italicized font*. Assignee's arguments immediately follow in regular font.

Claims 20-31 are rejected under 35 U.S.C. 101 because the claimed method is not tied to a particular structure. The steps of performing a time/frequency analysis must be tied to a specific structure or machine.

Claim 1 recites "receiving, in a controller, a flow signal from an implanted flow sensor, the flow signal indicative of an instantaneous flow waveform; analyzing the flow waveform in both the time domain and frequency domain; and outputting, from the controller, a control signal to control an implanted blood pump in response to the analysis of the flow waveform".

As previously argued, the Board of Patent Appeals and Interferences recently held that "a computerized method which includes a step of outputting information from a computer [is] tied to a particular machine or apparatus". *Ex Parte Dickerson*, Appeal 2009-001172 (BPAI 2009). In the present case, claim 20 recites "outputting, from the controller, a control signal..." Thus, the Board has already ruled on this issue and agrees with Assignee that the claims are "tied to a particular machine or apparatus". The recent United States Supreme Court ruling in *Bilski* merely held that this "machine or transformation" test is not the only test. Of course, in the present case, the claims meet this test, and are therefore, directed to patent eligible subject matter. For at least these reasons, Assignee respectfully submits that claim 20 is patentable. Reconsideration and withdrawal of this rejection is requested.

Claims 20-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification appears to be silent regarding the method step of analyzing the flow waveform in both the time domain and frequency domain.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Paragraph [0029] of the specification states:

[0029] U.S. Provisional Patent Application Nos. 60/346,555 and 60/319,318, filed on Jan. 8, 2002, and Jun. 14, 2002 respectively, both entitled "METHOD AND. SYSTEM FOR DETECTING VENTRICULAR COLLAPSE," disclose methods of detecting ventricular collapse, or excess suction. U.S. Provisional Application No. 60/346,721, filed on Jan. 7, 2002, discloses physiologic pump control methods based on diastolic flow, among other things. The entire disclosures of these

provisional applications are incorporated by reference herein.

On page 12, line 11, through page 13, line 12, U.S. Provisional Patent Application No. 60/346,555 teaches:

Embodiments of the present invention employ various mechanisms to detect the onset and/or presence of ventricular collapse based on the processing and/or analysis of certain inherent pump system parameters (e.g. flow, current, speed, etc.). These analysis techniques are performed in the time domain and frequency domain. Time domain mechanisms include correlation techniques as well as linear and non-linear signal processing. Frequency domain mechanisms include various real-time spectral analysis methods using Fourier Transforms such as the Fast Fourier Transform ("FFT") and the Discrete Fourier Transform ("DFT"), as well as other linear and non-linear signal processing techniques.

In the time domain, a physiologically appropriate flow(t) waveform is assumed to be quasi-sinusoidal at a single frequency proportional to the patient's native heart rate (i.e. fundamental frequency). In the frequency domain, the corresponding physiologically appropriate flow(f) waveform will be a single narrow spectral peak at the same single frequency proportional to the patient's native heart rate. As the flow(t) waveform becomes more distorted (i.e. deviates from a perfect sinusoid), the flow(f) waveform will contain additional spectral peaks corresponding to flow contributions at varying frequencies.

The Fourier Series may be used to compute the fundamental and harmonic components from time domain signals that are continuous and periodic. Many in vivo waveforms that may denote suction, however, are not periodic, and further, the frequency components of such waveforms may not be harmonically related to the fundamental frequency. In accordance with aspects of the present invention, many frequency components, both harmonically related and not, about the fundamental are analyzed to precisely detect suction.

These paragraphs have been explicitly added to the instant specification and Assignee believes doing so resolves any possible written description and/or antecedent basis issues that may have existed. However, because this disclosure was explicitly incorporated by specific reference, Assignee does not accede that there were written description and/or antecedent basis issues. Finally, because this disclosure was explicitly incorporated by specific reference, these amendments to the specification do no constitute new matter. Additional support may be

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found in U.S. Provisional Patent Application Nos. 60/346,555, 60/319,318, and/or 60/346,721.

However, Assignee currently believes the above to be more than sufficient.

Claim 20 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,396,327. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are directed to obvious variations of controlling a blood pump by analyzing a flow waveform or signal in both a time domain and a frequency domain.

Assignee does not accede that the claims are not patentably distinct. However, in an effort to advance prosecution, Assignee stands ready to file a terminal disclaimer, should no other grounds of rejection be sustained for Appeal.

*Claims 20, 22, 26-29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (US 4989609).
As to claim 20, Smith discloses a method of controlling a blood pump, comprising: receiving, in a controller, a flow signal from an implanted flow sensor, the flow signal indicative of an instantaneous flow waveform; analyzing the flow waveform in both the time domain and frequency domain; and outputting, from the controller, a control signal to control an implanted blood pump in response to the analysis of the flow waveform (Figs. 3, 7; col. 8 ll. 1-35).*

As an initial matter, Assignee does not accede to the Office's characterization of Smith as applied to the claims and Assignee respectfully reserves its right to present additional challenges that characterization in the future.

"A claim is anticipated only if each and every element as set forth in claim is found, either expressly or inherently described, in a single prior reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 631 (Fed. Cir. 1987). As the Court of Appeals for the Federal Circuit has held, "The test for anticipation is whether the claim reads on the product or process disclosed in the prior art, **not on what that reference broadly teaches.**" *SSIH Equip. S.A. v. United States Int'l Traded Comm'n*, 718 F.2d 365, 218 USPQ 678 (Fed. Cir. 1983) (emphasis

added). Further, the law of anticipation requires that the prior art reference disclose each claim limitation **arranged as in the claim**. See, e.g., *Brown v. 3M*, 265 F.3d 1349, 60 USPQ2d 1375 (Fed. Cir. 2001)("to anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim"); *Karsten Mfg. Corp. v. Cleveland Golf* 242 F.3d 1376, 1383 (Fed. Cir. 2001); *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 47 USPQ2d 1225 (Fed. Cir. 1998)("a finding of anticipation requires that the publication describe all of the elements of the claims, arranged as in the patented device."); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990)("These elements must be arranged as in the claim under review."). The Office may not establish anticipation by mere "substantial similarity" between the prior art disclosure and the arrangement of claim limitations. See *Jamesbury Corp. v. Litton Indus. Prods., Inc.*, 756 F.2d 1556, 225 USPQ 253 (Fed. Cir. 1985). Rather, the Office may reject a claim as anticipated **only** when each and every claim limitation must be described identically in the single prior art reference. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

Claim 20 recites "receiving, in a controller, a flow signal from **an implanted flow sensor**, the flow signal indicative of an instantaneous flow waveform; analyzing the flow waveform in **both the time domain and frequency domain**; and outputting, from the controller, a control signal to control **an implanted blood pump** in response to the analysis of the flow waveform", emphasis added.

In contrast, Smith appears to be completely devoid of any implanted flow sensor and/or blood pump, and therefore cannot receive "a flow signal from **an implanted flow sensor**," as claimed, or output "a control signal to control **an implanted blood pump**", as claimed. In fact, it appears, as best understood, that Smith's source 10, tubing 20, and demodulator 34, along with other associated components, are all external to any body. Assignee has certainly found no

explicit teaching of them being implanted, as required by the claim. Furthermore, Smith merely appears to teach determining an accurate flow rate, rather than performing any sort of pump control. Therefore, Smith appears to be devoid of outputting any control signal.

Finally, rather than "analyzing the flow waveform in ***both the time domain and frequency domain***", as required by the claim, Smith explicitly admits that his "Doppler blood flow system calculates flow rate solely on the basis of frequency". Abstract. See also column 3, lines 10-12 ("the flowmeter of the present invention and the method invoked therein calculates flow rate solely on the basis of frequency"). Therefore, it appears that Smith is completely devoid of each of the three claimed method steps. At the very least, Smith does not disclose each of the claim limitations, ***arranged as in the claim***. For at least these reasons, Assignee respectfully submits that claim 20 is patentable over the disclosure and teaching of Smith. Reconsideration and withdrawal of this rejection is requested.

This Office Action has improperly been made Final. The currently pending claims were presented in the amendment filed March 3, 2010. They were rejected under 102(b) as being anticipated by Ash in the Office Action dated June 9, 2010. Arguments were presented, ***but no claim amendments were made***, in the amendment filed July 23, 2010. In this Office Action, the previous rejections based on Ash have been withdrawn and entirely new grounds of rejection are being presented. Thus, it is wholly improper to make this a Final Office Action.

3. Conclusion

In responding to this Office Action, Assignee has presented only those arguments and made only those amendments that Assignee believes are warranted. Assignee has not, for example, responded to every factual or legal issue raised by the Office, and Assignee has not presented every argument supporting patentability that may be relevant. The decision not to

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address a factual or legal issue raised or to present a certain argument in support shall not be construed as Assignee's agreement with the Office on such issue or effect a waiver of Assignee's right to address such issues or make such arguments in the future.

Claims 20-31 are currently pending in this application. Assignee submits that each claim presented herein is patentable. A timely notice of allowance is respectfully requested.

Assignee thanks the Examiner for his/her consideration and effort on this file. If there are any questions or if additional information is needed, the Examiner is invited to telephone or email the undersigned.

Respectfully submitted,

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